

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE)	
PHARMACEUTICALS L.P., and)	
GRÜNENTHAL GMBH,)	
)	
Plaintiffs,)	
v.)	C.A. No. _____
)	
AMNEAL PHARMACEUTICALS, LLC,)	
)	
Defendant.)	

COMPLAINT

Plaintiffs, Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, “Purdue”) and Grünenthal GmbH (“Grünenthal”) (collectively, “Plaintiffs”), for their Complaint against Defendant Amneal Pharmaceuticals, LLC (“Amneal”), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,763,886 (the “’886 patent”), 9,763,933 (the “Mannion ’933 patent”),¹ and 9,675,610 (the “’610 patent”) (collectively, “the patents-in-suit”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 203235 as amended (“Amneal’s Amended ANDA”) submitted, upon information and belief, in the name of Amneal to the United States Food and Drug Administration (“FDA”). Plaintiffs seek judgment that Amneal has infringed the ’886, Mannion ’933 and ’610 patents. The ’610 and Mannion ’933 patents are listed in the FDA *Approved Drug*

¹ The Mannion ’933 patent is different from U.S. Patent No. 9,073,933, which is one of the patents-in-suit in a related action pending in this Court, C.A. No. 1:15-cv-01152-RGA, and which has been referred to as the “’933 patent.” To avoid confusion, Plaintiffs refer to U.S. Patent No. 9,073,933 as the Kupper ’933 patent.

Products With Therapeutic Equivalence Evaluations (“Orange Book”) as covering Purdue’s OxyContin® (oxycodone hydrochloride) (“OxyContin®”), an extended-release pain medication. Amneal has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 203235 as amended, submitted upon information and belief in the name of Amneal to the FDA. Amneal’s Amended ANDA seeks approval to market a generic version of Purdue’s OxyContin®, which is the subject of approved NDA No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths (“Amneal’s Amended ANDA Products”).

2. On September 17, 2015, Purdue filed a related Complaint against Amneal, C.A. No. 15-831-RGA, for patent infringement of U.S. Patent Nos. 9,060,976 (the “’976 patent”) and 9,034,376 (the “’376 patent”). The previous action was filed in connection with Amneal’s ANDA No. 203235, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’976 patent, listed in the Orange Book as covering OxyContin®, is “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

3. On December 15, 2015, Plaintiffs filed a related Complaint against Amneal, C.A. No. 15-1152-RGA, for patent infringement of U.S. Patent Nos. 7,674,799 (the “’799 patent”); 7,674,800 (the “’800 patent”); 7,683,072 (the “’072 patent”); 8,114,383 (the “’383 patent”); 8,309,060 (the “’060 patent”); 8,337,888 (the “’888 patent”); 8,808,741 (the “’741 patent”); 8,894,987 (the “’987 patent”); 8,894,988 (the “’988 patent”); 9,060,976 (the “’976 patent”); 9,034,376 (the “’376 patent”); and 9,073,933 (the “Kupper ’933 patent”). The previous action was filed in connection with Amneal’s Amended ANDA, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the

'799, '800, '072, '383, '060, '888, '741, '987, '988, '976, '376 and Kupper '933 patents, listed in the Orange Book as covering OxyContin®, are “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

4. On March 1, 2017, Purdue filed a related Complaint against Amneal, C.A. No. 17-210-RGA, for patent infringement of United States Patent Nos. 9,492,392 (the “’392 patent”); 9,492,393 (the “’393 patent”); and 9,522,919 (the “’919 patent”). The previous action was filed in connection with Amneal’s ANDA, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’392, ’393, and ’919 patents, listed in the Orange Book as covering OxyContin®, are “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

THE PARTIES

5. Plaintiff Purdue Pharma L.P. (“Purdue Pharma”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the Mannion ’933 and ’886 patents. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

6. Plaintiff Purdue Pharmaceuticals L.P. (“Purdue Pharmaceuticals”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the Mannion ’933 and ’886 patents.

7. Plaintiff Grünenthal GmbH (“Grünenthal”) is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of the ’610 patent.

8. On information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd floor, Bridgewater, NJ 08807.

SUBJECT MATTER JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Amneal resides in this judicial district.

PERSONAL JURISDICTION

12. This Court has personal jurisdiction over Amneal by virtue of, *inter alia*, the fact that Amneal is a Delaware limited liability company, Amneal’s systematic and continuous contacts with Delaware, and Amneal’s contacts with Delaware in connection with the submission of its ANDA, as set forth below.

13. On information and belief, Amneal is registered to conduct business within the State of Delaware and maintains as a registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange St, Wilmington, Delaware 19801.

14. On information and belief, Amneal holds current and valid “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale” licenses from the Delaware Board of Pharmacy.

15. On information and belief, Amneal is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States.

16. On information and belief, Amneal has admitted to, consented to or has not contested, the jurisdiction of this Court, and/or has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of Delaware actions, *e.g.*, *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 17-210; *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-1152; *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-831; *Forest Laboratories, LLC v. Amneal Pharmaceuticals LLC*, C.A. No. 15-756; *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-697; *Forest Laboratories, LLC v. Amneal Pharmaceuticals LLC*, C.A. No. 15-430; *Merck Sharpe & Dohme Corp. v. Amneal Pharmaceuticals LLC*, C.A. No. 15-250; and *Forest Laboratories, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 14-508.

17. On information and belief, if ANDA No. 203235 as amended is approved, Amneal’s Amended ANDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

18. This Court further has personal jurisdiction over Amneal by virtue of the fact that Amneal has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

THE '886 PATENT

19. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '886 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '886 patent is attached hereto as Exhibit A, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE MANNION '933 PATENT

20. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the Mannion '933 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The Mannion '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the Mannion '933 patent is attached hereto as Exhibit B, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '610 PATENT

21. Grünenthal is the lawful owner of all right, title and interest in the '610 patent, titled "ABUSE-PROOFED DOSAGE FORM," including the right to sue and to recover for past infringement thereof. The '610 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '610 patent is attached hereto as Exhibit C, which was duly and legally issued on June 13, 2017, naming Johannes Bartholomaeus and Heinrich Kugelmann as the inventors.

AMNEAL'S AMENDED ANDA

22. On information and belief, on or before September 27, 2011, Amneal filed Amneal's ANDA No. 203235 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Amneal's ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Amneal subsequently submitted in its ANDA a "Paragraph IV" certification under 21 U.S.C. § 355U)(2)(A)(vii)(IV) alleging that the '976 patent, listed in the FDA's Orange Book as covering the OxyContin®, which is the subject of approved NDA No. 022272, is "invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of" the drug products described in Amneal's ANDA.

23. In a letter dated August 3, 2015, addressed to Plaintiffs and received by Purdue Pharma on or about August 4, 2015, Amneal provided what purports to be a "Notice of Paragraph IV Certification" with respect to Amneal's ANDA and Amneal's Amended ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

24. On information and belief, on or before October 30, 2015, Amneal filed Amneal's Amended ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Amneal's Amended ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Amneal's Amended ANDA contained a "Paragraph IV" certification under 21 U.S.C. § 355(U)(2)(A)(vii)(IV) alleging that the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976 and '933 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation" of the drug products described in Amneal's Amended ANDA.

25. In a letter dated October 30, 2015, addressed to Plaintiffs and received by Purdue Pharma on or about November 2, 2015, Amneal provided what purports to be a "Notice of Paragraph IV Certification" with respect to Amneal's Amended ANDA and Amneal's Amended ANDA Products, and the '799, '800, '072, '383, '060, '888, '741, '987, '988, '976 and '933 patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

26. On information and belief, on or before January 16, 2017, Amneal filed Amneal's Amended ANDA No. 203235 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Amneal's Amended ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Amneal's Amended ANDA contained a "Paragraph IV" certification under 21 U.S.C. § 355(U)(2)(A)(vii)(IV) alleging, *inter alia*, that the '392, '393 and '919 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved

NDA No. 022272, are “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation” of the drug products described in Amneal’s Amended ANDA.

27. In a letter dated January 16, 2017, addressed to Purdue and received by Purdue Pharma on or about January 17, 2017, Amneal provided what purports to be a “Notice of Paragraph IV Certification” with respect to Amneal’s Amended ANDA and Amneal’s Amended ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

28. On information and belief, on or before August 23, 2017, Amneal filed Amneal’s Amended ANDA No. 203235 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Amneal’s Amended ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Amneal’s Amended ANDA contained a “Paragraph IV” certification under 21 U.S.C. § 355(U)(2)(A)(vii)(IV) alleging, *inter alia*, that the ’610 patent, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation” of the drug products described in Amneal’s Amended ANDA.

29. In a letter dated August 23, 2017, addressed to Plaintiffs and received by Purdue Pharma on or about August 24, 2017, Amneal provided what purports to be a “Notice of Paragraph IV Certification” with respect to Amneal’s Amended ANDA and Amneal’s Amended

ANDA Products, and the '610 patent, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

30. Plaintiffs commenced this action within the 45-day period after receiving the Notice Letter dated August 23, 2017, as described in 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,886)

31. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

32. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 203235, as amended, to the FDA seeking approval of Amneal's Amended ANDA Products was an act of infringement of the '886 patent by Amneal.

33. The manufacture of Amneal's Amended ANDA Products, or the sale, offer for sale, or use thereof, are covered by one or more claims of the '886 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of producing a plurality of solid oral extended release pharmaceutical dosage forms comprising the steps of: mixing at least one active agent, at least one high molecular weight polyethylene oxide (PEO) having an approximate molecular weight of from 1 million to 15 million, to provide a PEO composition; compressing the PEO composition to provide a plurality of shaped matrix compositions; curing the shaped matrix compositions by exposure to heated air at a curing temperature that is at least the softening temperature of the high molecular weight PEO for a curing time of at least about 5 minutes, to provide a plurality of cured matrix compositions; cooling the cured matrix compositions; wherein (a) the molecular weight of each PEO is based on rheological measurements; (b) the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form; (c) the total weight of each dosage form is calculated by excluding the

combined weight of said film coatings; and (d) each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent.

34. If approved by the FDA, Amneal will infringe the '886 patent by making, using, offering for sale, selling, and distributing products embodying the patented inventions in violation of 35 U.S.C. § 271(a) or (g) and/or by inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b).

35. Amneal, through at least its labeling and manufacturing process, will intentionally induce infringement of the '886 patent by at least patients who will take Amneal's Amended ANDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Amneal who manufacture Amneal's Amended ANDA Products.

36. Upon information and belief, Amneal has been aware of the existence of the '886 patent and has no reasonable basis for believing that the manufacture, use, sale, or offer for sale of Amneal's Amended ANDA Products will not infringe the '886 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

37. Unless Amneal is enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Amneal's infringement of the '886 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,933)

38. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 37 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 203235 as amended to the FDA seeking approval of Amneal's Amended ANDA Products was an act of infringement of the Mannion '933 patent by Amneal.

40. Amneal's Amended ANDA Products, or the use thereof, are covered by one or more claims of the Mannion '933 patent, including but not limited to independent claim 1, which recites, *inter alia*, a pharmaceutical composition comprising: at least one active agent; at least one high molecular weight polyethylene oxide (PEO) having an approximate molecular weight of from 1 million to 15 million; wherein (a) the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular weight PEO, (iii) cooled, and (iv) hardened; (b) the high molecular weight PEO comprises at least about 30% (by weight) of the dosage form; (c) the molecular weight of each PEO is based on rheological measurements; and (d) the total weight of the dosage form is calculated by excluding the combined weight of said film coatings.

41. If approved by the FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of Amneal's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the Mannion '933 patent under 35 U.S.C. § 271(a)-(c).

42. Amneal's ANDA Products constitute a material part of the inventions covered by the claims of the Mannion '933 patent.

43. Upon information and belief, Amneal has been aware of the existence of the Mannion '933 patent and has no reasonable basis for believing that Amneal's Amended

ANDA Products will not infringe the Mannion '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

44. Unless Amneal is enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Amneal's infringement of the Mannion '933 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,675,610)

45. Plaintiffs incorporate by reference and reallege paragraphs 1 through 44 above as though fully restated herein.

46. Pursuant to 35 U.S.C. § 271(e)(2), Amneal's submission of ANDA No. 203235 as amended to the FDA seeking approval of Amneal's Amended ANDA Products was an act of infringement of the '610 patent by Amneal.

47. Amneal's Amended ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '610 patent, including but not limited to independent claim 1, which recites, *inter alia*, a solid dosage form for oral administration with reduced potential for parenteral abuse, said dosage form comprising: (a) one or more active ingredients having potential for abuse selected from the group consisting of (among others) oxycodone and a pharmaceutically acceptable salt thereof; and (b) one or more viscosity-increasing agents in a quantity such that an aqueous extract of a total content of the dosage form when comminuted and combined with 10 ml of water at 25° C forms a gel that can be drawn up into and injected back out of a hypodermic needle having a diameter of 0.9 mm, into a further quantity of water, wherein threads of the gel injected from said needle remain visible to the naked eye in said further quantity of water at 37° C.

48. If approved by the FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of Amneal's Amended ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '610 patent under 35 U.S.C. § 271(a)-(c).

49. Amneal's Amended ANDA Products constitute a material part of the inventions covered by the claims of the '610 patent.

50. Upon information and belief, Amneal has been aware of the existence of the '610 patent and has no reasonable basis for believing that Amneal's Amended ANDA Products will not infringe the '610 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

51. Unless Amneal is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Amneal's infringement of the '610 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Amneal has infringed one or more claims of each of the '886, Mannion '933 and '610 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Amneal's Amended ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '886, Mannion '933 and '610 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203235 as amended and Amneal's Amended ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier

than the last date of expiration of the '886, Mannion '933, and '610 patents, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Amneal, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 203235 as amended, including Amneal's Amended ANDA Products or any other drug product that infringes the '886, Mannion '933 and '610 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

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